

### **REMARKS**

Review and reconsideration of the final Office Action mailed May 13, 2008 (hereinafter "Office Action"), is respectfully requested in view of the above amendments and the following remarks. At the time of the Office Action, claims 10 and 12-19 were pending. Claims 10 and 12-19 were rejected under one or more of 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 103(a). By this Amendment, claims 10 and 17 are amended, claim 12 is cancelled, and claim 20 is added. No new matter is added.

### **Amendments to the Claims**

By this Amendment, claims 10 and 17 are amended to incorporate limitations from cancelled claim 12. New claim 20 is drawn to subject matter already recited in claims 17 and 18. No new matter is added.

### **Claims Rejections – 35 USC § 112, second paragraph**

In the Office Action, claims 10-19 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that the phrase "castor oil derivative" is indefinite because it encompasses a large number of compounds that would reasonably be expected to alter the physical and chemical properties, physiological effects and functions, of the compound.

The claim currently recites a "cosmetically useful castor oil derivative." In assessing whether a claim is indefinite, the Manual of Patent Examination Procedure instructs that:

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

MPEP 2173.02.

The definiteness requirement under 35 U.S.C. §112, second paragraph, are designed to ensure that a person of ordinary skill in the art can understand how to avoid infringement, *i.e.*, such a person can determine if what they are doing is infringing, *see* MPEP 2173.02; *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). This does not require that the person of ordinary skill in the art would be able to envision every possible variation covered by the claim language, only that they would know if a specific composition was encompassed by the claim language. In this case, it would be apparent to a person of ordinary skill in the art if the thickener they chose was a "castor oil derivative" regardless of the expected differences in physical and chemical properties, physiological effect and function cited in the Office Action.

This is further demonstrated by the CTFA (Cosmetic, Toiletry and Fragrance Association) 2000 International Buyers' Guide, which demonstrates that INCI names of cosmetic ingredients in the Buyers' Guide clearly identify castor oil derivatives. Clearly, the claim limitation meets the definiteness requirement of 35 U.S.C. §112, second paragraph, because a person of ordinary skill in the art would be able to easily determine whether they were including a castor oil derivative in their composition or not.

The Examiner asserts that "any significant variation would be reasonably expected to alter the compound, *e.g.*, physical, chemical, physiological effect and functions," Office Action, page 3. While this may be true, such variations do not prevent a person of ordinary skill in the art from determining whether the compound is a castor oil derivative or not. Furthermore, individuals of ordinary skill in the art recognize the difference between functional groups which are cosmetically acceptable and those that are not. Accordingly, Applicants assert that the claims meet the requirements of 35 U.S.C. §112, second paragraph, and respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

#### **Claims Rejections – 35 U.S.C. § 103**

In the Office Action, claims 10-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over PCT Publication WO 86/05389 to Mackles (hereinafter "Mackles WO") in view of U.S. Patent No. 4,708,812 issued to Hatfield (hereinafter "Hatfield") and U.S. Patent No. 6,274,128 issued to Bergmann *et al.* (hereinafter "Bergmann"). Claims 17-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mackles in view of Hatfield and Bergmann, and further in view of U.S. Patent No. 5,322,683 issued to Mackles *et al.* (hereinafter "Mackles US").

Prior to addressing the cited references, Applicants wish to review the claimed cosmetic self-warming product as set forth in claim 10, which recites:

10. (currently amended) A cosmetic self-warming product for skin cleansing, comprising a composition which is substantially water-free and contains:

0.1 to 40 % by weight of a hydrophilic aluminum-rich zeolite with a pore size in the range of 0.3 to 0.5 nm,

1 to 99 % by weight of a disperse oil phase, selected from the group consisting of triglycerides, silicone oils and mixtures thereof,  
0.1 to 50 % by weight of a non-ionic surface-active agent,  
0.1 to 40 % by weight of an emollient,  
0.1 to 20 % by weight of a thickener, selected from the group consisting of polyethylene, 12-hydroxy stearic acid, cosmetically useful castor oil derivatives and waxes, and  
ad 100 % by weight cosmetic carrier substances, auxiliary substances, active substances and mixtures thereof,  
with the proviso that no polyvalent alcohols and polar solvents are contained in the product, wherein the product contains a zeolite with a ratio Si/Al in the range of 2-5:1.

The claimed self-warming cosmetic includes 0.1 to 20 wt-% of a thickener selected from the group consisting of polyethylene, 12-hydroxy stearic acid, cosmetically useful castor oil derivatives and waxes. This list is limited to liquid thickeners and no longer includes clay. In addition, the claimed self-warming cosmetic also requires a zeolite with an Si/AL ratio in the range of 2:1 to 5:1. As demonstrated by the previously submitted Declaration of Co-Inventor Donna Hui-Ing Hwang Under 37 C.F.R. §1.132 (hereinafter "Hwang Declaration"), this ratio has a substantial impact on the heating effect. Furthermore, the claimed Si/Al range is capable of producing the claimed 4 to 8 K skin temperature increase found in independent claim 17 and a similar limitation is found in new claim 20.

Applicants respectfully assert that the cited references do not disclose or suggest at least the claimed features of (i) a thickener selected from the group consisting of polyethylene, 12-hydroxy stearic acid, cosmetically useful castor oil derivatives and waxes, (ii) a zeolite with an Si/AL ratio in the range of 2:1 to 5:1, (iii) a zeolite capable of producing the claimed 4 to 8K skin, or (iv) a combination thereof. These features are necessary to achieve the

silky feel described in the specification and the claimed skin-warming properties found in claims 17 and 20.

The Mackles WO reference is drawn to a stable, anhydrous aerosol foam that may contain a particulate solid capable of absorbing water exothermically. The anhydrous aerosol foam is prepared by combining particulate solids with a foamable liquid oil, a foaming agent and a propellant, *see* Mackles WO, Abstract.

The Office Action acknowledges that Mackles WO fails to disclose the specifically claimed thickeners, but relies on Hatfield solely for disclosing clay as a thickener. ***Applicants note that clay is not included in the list of claims thickener.*** As clay is the only one of the claimed thickeners purportedly disclosed by the cited references, Applicants respectfully request that the instant rejection be withdrawn.

As noted in the Office Action, the zeolites in Mackles WO are silicon-rich zeolites with an Si:Al ratio of 1.1 to 0.1, *i.e.*, 1:0.9 to 1:10. The silicon-rich zeolites disclosed in Mackles WO are typically used as washing powders. In contrast, zeolites of the current invention are aluminum-rich with a preferred Si:Al ratio of 2:1 to 5:1, *see* Specification, paragraph [0016] & claims 10 and 17. As demonstrated by the results of the Hwang Declaration, this produces substantially different skin heating characteristics, *see* Hwang Declaration, section 4. Although Applicants have now demonstrated that this ratio is critical (which was not the case prior to the filing of the instant application), the Office Action fails to address this difference in the Si/Al ratio.

As demonstrated by the Hwang Declaration, the zeolites disclosed by Mackles WO, *i.e.*, VALFOR® 950, are not capable of producing the claimed skin temperature increase, *see* Hwang Declaration, section 4. The Examiner argues that the data submitted by Dr. Hwang

has "no probative value" "unless comparison is made with disclosure identical (not similar) with that of the reference," Office Action, page 7.

In this regard, Applicants bring MPEP 716.02(e) to the Examiner's attention. MPEP 716.02(e) states, in relevant part, that:

Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, *In re Finley*, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. *In re Armstrong*, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential).

MPEP 716.02(e).

In this case, the only specific zeolite disclosed by Mackles WO is VALFOR® 950, *see* Mackles WO, Examples 1-7. Thus, the data submitted via the Hwang Declaration is drawn to the results of VALFOR® 950 compared to a zeolite with the claimed Si:Al ratio. The differences between the Mackles WO Examples and the VALFOR® 950 raw material tested by Dr. Hwang is the addition of cosmetic ingredients that have no impact on quantity of energy liberated by the zeolite-water reaction. Thus, as explained by Dr. Hwang, the test results described in the Hwang Declaration "demonstrate the best case temperature rise, because they deal with pure zeolite," Hwang Declaration, section 4.

Dr. Hwang's statement is apparent to a person of ordinary skill in the art based on the following logic. The reaction of a given amount of zeolite with a given amount of water will liberate a particular quantity of energy. This liberated energy produces a temperature increase in the materials surrounding the zeolite. The magnitude of the temperature increase will decrease (i) as the amount of material contacting the zeolite increases, and (ii) with distance from the zeolite. Thus, because the presence of the additional ingredients found in Examples 1-7 can only result in a smaller temperature increase than that measured in Dr.

Hwang's tests, Dr. Hwang concluded that the test results "demonstrate the best case temperature rise, because they deal with pure zeolite," Hwang Declaration, section 4.

*Accordingly, while the Hwang Declaration does not test the exact compositions disclosed in the Mackles WO Examples, they provide even more critical evidence – evidence that the claimed temperature rise cannot be achieved using the zeolite disclosed in Mackles WO regardless of the remaining ingredients found in the Mackles WO cosmetic composition, see Hwang Declaration, section 4 ("Clearly, the composition produced by the suggested rejection, i.e. one using a zeolite equivalent to VALFOR® 950, is simply not capable of 'rais[ing] in temperature of the skin by 4 to 8 K during cleansing compared to the starting surface temperature of the skin.'"). Thus, properly interpreted in view of MPEP 716.02(e).III., Applicants submit that the data provided in the Hwang Declaration is sufficient to overcome the instant rejection.*

Bergmann is drawn to a method for conditioning hair with warming, which includes administering the conditioner composition of the Bergmann invention. The Bergmann conditioner compositions include a carrier material that can include polar solvents and multivalent alcohols, *see* Bergmann, col. 3, ln. 22-25; col. 3, ln. 66 – col. 4, ln. 4 & claims 5-8. The Bergmann conditioner compositions can also include up to 2 wt-% water. In contrast, the claimed cosmetic self-warming product for skin-cleansing expressly includes the "proviso that no polyvalent alcohols and polar solvents are contained" therein, claims 10, 17 & 20.

As discussed in the specification, polar solvents and multivalent alcohols reduce the water absorption potential of the zeolites, resulting in a significant reduction in the overall warming potential of the zeolite. Clearly, the combination of Mackles WO and Bergman

does not disclose or suggest at least the limitation that "no polyvalent alcohols and polar solvents are contained" in the claimed cosmetic self-warming product for skin-cleansing.

Hatfield is drawn to encapsulation of phase change materials for heat exchangers, can include clay or Carbosil M-5 as thickeners, *see* Hatfield, Abstract. Although Applicants believe that Hatfield is drawn to a nonanalogous art and is not reasonably pertinent to Applicants' cosmetic endeavors, *see* MPEP 2141.01(a), Applicants have decided not to pursue this argument in order to expedite prosecution of this application to allowance.

Applicants address Hatfield by noting that Hatfield is used to disclose the claimed thickeners. Applicants note that Hatfield is used for the disclosure of clay as a thickener, but the claimed thickeners are "selected from the group consisting of polyethylene, 12-hydroxy stearic acid, cosmetically useful castor oil derivatives and waxes." As Hatfield does not disclose or suggest any of these thickeners, the instant rejection fails to establish a *prima facie* case of obviousness and Applicants respectfully request that the instant rejection be withdrawn.

Turning to Mackles US, which the Office Action asserts discloses a self-heating foam composition comprising aluminosilicates useful as a hair conditioner and facial cleanser. Mackles US is apparently used solely to assert that the compositions disclosed by Mackles WO could be used as part of a method for skin cleansing. This simply does not suffice to remedy the deficiencies identified above.

Applicants now provide a more detailed discussion of the Hwang Declaration. The claimed method (and the product of claim 20) disclose that the composition is "formulated to cause a raise in temperature of the skin by 4 to 8 K during cleansing compared to the starting surface temperature of the skin." Mackles WO discloses zeolites with silicon-rich zeolites with an Si:Al ratio of 1.1 to 0.1, *i.e.*, 1:0.9 to 1:0.1. Mackles WO uses VALFOR® 950, which presumably has an Si:Al ratio between 1.1 and 0.1, as the exemplary zeolite, *see* Mackles



WO, Examples 1-7 on p. 13 – 21. In order to demonstrate that the zeolite containing composition produced by the rejection is not capable of producing the claimed level of heating, Applicants have submitted comparative data in the Hwang Declaration.

As noted in Comparative Example #1 of the Hwang Declaration, when 100g of water are added to 45g of water-free VALFOR® 950, the temperature increase is  $4.1^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ . The current disclosure described compositions using aluminum-rich zeolites, such as MOLSIV® GMP3A, *see* Specification, paragraph [0029] & [0035]. As noted in Comparative Example #2 of the 132 Declaration, when 100g of water are added to 45g of water-free MOLSIV® GMP3A, the temperature increase is  $7.2^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$ . As explained in the Hwang Declaration, this is a significantly different temperature increase.

However, the compositions produced based on the cited references could include up to 5 wt-% water as well as multivalent alcohols and polar solvents. Comparative Example #2 of the Hwang Declaration, demonstrates the impact of adding as little as 5 mg of water to the 45 mg samples of Comparative Example #1. The addition of 5 mg of water to the silicon-rich VALFOR® 950 resulted in a temperature increase of  $1.2^{\circ}\text{C} \pm 0.31^{\circ}\text{C}$ ; while the same addition to the aluminum-rich MOLSIV® GMP3A resulted in a temperature increase of  $1.9^{\circ}\text{C} \pm 0.33^{\circ}\text{C}$ .

However, the more important information is the impact that the presence of water has on the zeolites when they are exposed to significant amounts of water, such as those used during face washing. Thus, the wetted zeolites were allowed to stand for 2 hours before they were contacted by 100g of water. The addition of 100 mg of water to the pre-treated silicon-rich VALFOR® 950 resulted in a temperature increase of only  $3.4^{\circ}\text{C} \pm 0.41^{\circ}\text{C}$ ; while the same addition to the pre-treated aluminum-rich MOLSIV® GMP3A resulted in a temperature increase of  $6.0^{\circ}\text{C} \pm 0.34^{\circ}\text{C}$ . Clearly, the composition produced by the suggested

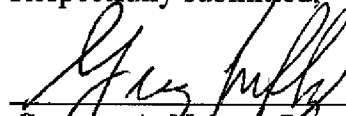
rejection is not capable of "rais[ing] in temperature of the skin by 4 to 8 K during cleansing compared to the starting surface temperature of the skin," *see* Hwang Declaration, section 4.

Clearly, none of the references, whether alone or in combination, disclose each of the claimed features of the claimed invention. Furthermore, there would be no motivation to combine the references in order to produce the claimed invention. This is particularly true with respect to claim 16 and because "clay," which was the lone link between Mackles WO and Hatfield, has been eliminated from the list of claimed list of thickeners.

#### **Conclusion**

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,



Gregory A. Nelson, Reg. No. 30,577  
Gregory M. Lefkowitz, Reg. No. 56,216  
AKERMAN SENTERFITT  
222 Lakeview Avenue, Suite 400  
West Palm Beach FL 33401  
Telephone: 561.653.500

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